

SIU 7398  
PATENT



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of Kathleen C.M. Campbell

Art Unit 1614

Serial No. 10/694,448

Filed October 27, 2003

Confirmation No. 8896

For THERAPEUTIC USE OF METHIONINE TO REDUCE THE TOXICITY OF  
PLATINUM-CONTAINING ANTI-TUMOR COMPOUNDS

Examiner Rebecca Cook

February 28, 2005

COMMISSIONER FOR PATENTS  
P.O. BOX 1450  
ALEXANDRIA, VIRGINIA 22313-1450

SIR:

**INFORMATION DISCLOSURE STATEMENT**

In accordance with 37 C.F.R. 1.97 and 1.98 and MPEP 609, and in compliance

\* with the duty of disclosure set forth in 37 C.F.R. 1.56, applicant submits the attached  
PTO/SB/08A for consideration by the Patent and Trademark Office in the above-  
entitled application and to be made of record therein.

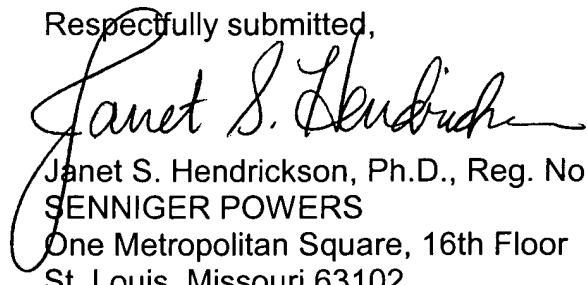
Applicant submits herewith copies of the prosecution history for the analogous  
grandparent and great-grandparent applications.

03/02/2005 SSITHIB1 00000088 10694448

02 FC:1806

180.00 OP

Respectfully submitted,



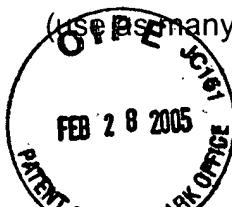
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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

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Sheet

1

of

2

**Complete if Known**

Application Number	10/694,448
Filing Date	October 27, 2003
Confirmation Number	8896
First Named Inventor	Kathleen C.M. Campbell
Group Art Unit	1614
Examiner Name	Rebecca Cook

Attorney Docket No. SIU 7398

**OTHER ART - NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>6</sup>
	78	Claims as filed in grandparent application Serial No. 09/057,065 filed on April 8, 1998 (pages 59-64).	
	79	Office action, Paper #4 issued June 3, 1999 in grandparent application Serial No. 09/057,065 filed on April 8, 1998.	
	80	Response to Restriction and Election of Species filed July 6, 1999 in grandparent application Serial No. 09/057,065 filed on April 8, 1998 (page 1 only).	
	81	Office action, Paper #7 issued October 14, 1999 in grandparent application Serial No. 09/057,065 filed on April 8, 1998.	
	82	Amendment A filed February 14, 2000 in grandparent application Serial No. 09/057,065 filed on April 8, 1998 (page 1 only).	
	83	Office action, Paper #10 issued June 14, 2000 in grandparent application Serial No. 09/057,065 filed on April 8, 1998.	
	84	Amendment B After Final Rejection filed August 11, 2000 in grandparent application Serial No. 09/057,065 filed on April 8, 1998 (pages 1-4 only).	
	85	Advisory action, Paper #12 issued September 11, 2000 in grandparent application Serial No. 09/057,065 filed on April 8, 1998.	
	86	Notice of Allowance, Paper #15 issued February 16, 2001 in grandparent application Serial No. 09/057,065 filed on April 8, 1998.	
	87	Claims as filed in great-grandparent application Serial No. 08/942,845 filed on October 2, 1997 (pages 52-59).	
	88	Office action, Paper #4 issued May 29, 1998 in great-grandparent application Serial No. 08/942,845, filed on October 2, 1997.	

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Group Art Unit	1614
Examiner Name	Rebecca Cook

Sheet	2	of	2	Attorney Docket No.	SIU 7398
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	89	Response to Election of Species Requirement and Amendment A filed June 5, 1998 in great-grandparent application Serial No. 08/942,845, filed on October 2, 1997 (pages 1-2 only).	
	90	Office action, Paper #6 issued July 1, 1998 in great-grandparent application Serial No. 08/942,845, filed on October 2, 1997.	
	91	Amendment B, Response Under 37 C.F.R. 1.111 filed October 1, 1998 in great-grandparent application Serial No. 08/942,845, filed on October 2, 1997 (pages 1-2 only).	
	92	Office action, Paper #10, issued January 1, 1999 in great-grandparent application Serial No. 08/942,845, filed on October 2, 1997.	
	93	Amendment C filed March 8, 1999 in great-grandparent application Serial No. 08/942,845, filed on October 2, 1997 (page 1 only).	
	94	Office action, Paper #13, issued April 9, 1999 in great-grandparent application Serial No. 08/942,845, filed on October 2, 1997.	
	95	Preliminary Amendment filed July 6, 1999 in great-grandparent application Serial No. 08/942,845, filed on October 2, 1997 (pages 1-7 only).	
	96	Office action, Paper #17, issued August 6, 1999 in great-grandparent application Serial No. 08/942,845, filed on October 2, 1997.	
	97	Amendment D filed February 4, 2000 in great-grandparent application Serial No. 08/942,845, filed on October 2, 1997 (pages 1-6 only).	
	98	Notice of Allowance, Paper #21 issued May 3, 2000 in great-grandparent application Serial No. 08/942,845 filed on October 2, 1997.	

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		First Named Inventor	Campbell	
		Group Art Unit	not yet assigned	
Sheet	1	of	8	Attorney Docket No.
SIU 7398				

**U.S. PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY
		Number	Kind Code <sup>2</sup> (if known)		
	1	2,732,400		Weiss	01-24-1956
	2	4,426,372		Borch	01-17-1984
	3	5,002,755		Mitchell et al.	03-26-1991
	4	5,292,773		Hirsch et al.	03-08-1994
	5	5,430,064		Hirsch et al.	07-04-1995
	6	5,466,678		Kawabata et al.	11-14-1995
	7	6,177,434		Kopke et al.	01-23-2001

**FOREIGN PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	T <sup>6</sup>
		Office	Number <sup>4</sup>	Kind Code <sup>2</sup> (if known)			
	8	EP	06 200 04	A1	Fuji Kagaku Kogyo Kabushiki Kaisha	10-19-1994	

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	9	ALDEN, W. WESLEY et al., "Exacerbation of Cisplatin-Induced Nephrotoxicity by Methionine," <u>Chem.-Biol. Interactions</u> , 1984, 48, Pgs. 121-124			T <sup>6</sup>
	10	BASINGER, MARK A. et al., "Dithiocarbamate-Induced Biliary Platinum Excretion and the Control of cis-Platinum Nephrotoxicity," <u>Toxicology and Applied Pharmacology</u> , 1989, 97, Pgs. 279-288			
	11	BASINGER, MARK A. et al., "L-Methionine Antagonism of cis-Platinum Nephrotoxicity," <u>Toxicology and Applied Pharmacology</u> , 1990, 108, Pgs. 1-15			
	12	BASINGER, MARK A . et al., "L-Methionine Suppresses Pathological Sequelae of cis-Platinum in the Rat," <u>Fundamental and Applied Toxicology</u> , 1990, 14, Pgs. 568-577			
	13	BOOGAARD, PIETER J. et al., "4-Methylthiobenzoic Acid Reduces Cisplatin Nephrotoxicity In Rats Without Compromising Anti-Tumor Activity, <u>Biochemical Pharmacology</u> , 1991, Vol. 41, No. 12, Pgs. 1997-2003			
	14	BOOGAARD, PIETER J. et al., "The Role of Methallothionein in the Reduction of Cisplatin-Induced Nephrotoxicity by Bi <sup>3+</sup> -Pretreatment in the Rat <i>In Vivo</i> and <i>In Vitro</i> , Are Antioxidant Properties of Methallothionein More Relevant than Platinum Binding?", <u>Biochemical Pharmacology</u> , 1991, Vol. 41, No. 3, Pgs. 369-375			
	15	BURCHENAL, JOSEPH H. et al., "Studies of Cross-Resistance, Synergistic Combinations and Blocking of Activity of Platinum Derivates," <u>Biochimie</u> , 1978, 60, No. 9, Pgs. 961-965			
	16	CAMPBELL, KATHLEEN C.M. et al., "A Review of Cisplatin Protective Agents Emphasizing Nephro- and Otoprotectants," <u>Proposed Review Article Not Yet Submitted for Publication, Including Additional Reference Lists</u>			
	17	CAMPBELL, KATHLEEN C.M. et al., "D-Methionine Provides Excellent Protection from Cisplatin Ototoxicity in the Rat," <u>Hearing Research</u> , 1996, 102, Pgs. 90-98			

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18	CAMPBELL, KATHLEEN C.M. et al., "D-Methionine Provides Protection Against Cisplatin Damage the Rat Stria Vascularis: A Semi-Quantitative Analysis," <u>Abstracts of the Twenty-First Annual Mid-Winter Research Meeting of the Association for Research in Otolaryngology</u> , February 15-19, 1998, Abstract No. 537, Pgs. 135	
19	CARDINI, G. et al., "La Radioprotezione Dei Cromosomi Delle Cellule Midollari Umane In Vitro," <u>Radiobiologia Radioterapia E Fisica Medica</u> , 1967, Vol. 22, No. 6, Pgs. 371-375	
20	CARRITHERS, S. L. et al., "Methylation Of Radiation Protector Compounds By Thiol Methyltransferase," <u>FASEB</u> , 1991, Vol. 5, No. 4, Pg. A824	
21	CHURCH, MICHAEL W. et al., "The Comparative Effects of Sodium Thiosulfate, Diethyldithiocarbamate, Fosfomycin and WR-2721 on Ameliorating Cisplatin-Induced Ototoxicity," <u>Hearing Research</u> , 1995, 86/1,2, Pgs. 195-203	
22	CORREA, J. N. et al., "Radiosensitization and radioprotection on murine chondrosarcoma," <u>Radiation Research</u> , 1978, Vol. 74, No. 3, Pg. 517	
23	DE VECCHI, A., "Sperimentazione Clinica Di Una Nuova Sostanza Radioprotettiva (Cloruro Di Metil-Metionin-Sulfonio)," <u>Radiobiologia Radioterapia E Fisica Medica</u> , 1967, Vol. 22, No. 5, Pgs. 355-370	
24	DEDON, PETER C. et al., "Characterization of the Reactions of Platinum Antitumor Agents with Biologic and Nonbiologic Sulfur-Containing Nucleophiles," <u>Biochemical Pharmacology</u> , 1987, Vol. 36, No. 12, Pgs. 1955-1964	
25	DEEGAN, PATRICIA M. et al., "The nephrotoxicity, cytotoxicity and renal handling of a cisplatin-methionine complex in male Wistar rats," <u>Toxicology</u> , 1994 , 89, Pgs. 1-14	
26	DREWINKO, B. et al., "The Effect of <i>cis</i> -Diamminedichloroplatinum(II) on Cultured Human Lymphoma Cells and Its Therapeutic Implications," <u>Cancer Research</u> , December 1973, 33, Pgs. 3091-3095	
27	DROBNIK, JAROSLAV et al., "Inactivation Of Bacteriophages With <i>Cis</i> -Platinum(II) Diamminedichloride," <u>Chem.-Biol. Interactions</u> , 1975, Pgs. 365-375	
28	FRIEDMAN, M. E. et al., "The Blocking Of The Tetrachloroplatinate(II) Inhibition Of Malate Dehydrogenase By Sulfur-Containing Amino Acids," <u>Biochimica et Biophysica Acta</u> , 1974, 341, Pgs. 277-283	

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29	FRIEDMAN, MENDEL et al., "The Utilization and Safety of Isomeric Sulfur-Containing Amino Acids in Mice," <u>J. Nutr.</u> , 1984, 114, Pgs. 2301-2310
30	GABAIZADEH, RAMIN et al., "Protection of Both Auditory Hair Cells and Auditory Neurons from Cisplatin Induced Damage," <u>Acta Otolaryngol</u> (Stockholm), 1997, 117, Pgs. 232-238
31	GANDARA, DAVID R. et al., "Cisplatin Chemoprotection and Rescue: Pharmacologic Modulation of Toxicity," <u>Seminars in Oncology</u> , February 1991, Vol. 18, No. 1, Suppl. 3, Pgs. 49-55
32	GANDARA, DAVID R. et al., "Evaluation of Cisplatin Dose Intensity: Current Status and Future Prospects," <u>Anticancer Research</u> , 1989, 9, Pgs. 1121-1128
33	GESSLER, N. et al., "Antiradiation effects of S-methylmethionine (Vitamin U)," <u>Prikl. Biokhim. Mikrobiol.</u> , 1996, Vol. 32, No. 6, Pgs. 666-668
34	GLOVER, DONNA et al., "Clinical Trials of WR-2721 and Cis-Platinum," <u>I. J. Radiation Oncology, Biology, Physics</u> , May 1989, Vol. 16, No. 5, Pgs. 1201-1204
35	HANNERMANN, JORG et al., "Cisplatin-Induced Lipid Peroxidation and Decrease of Gluconeogenesis in Rat Kidney Cortex: Different Effects of Antioxidants and Radical Scavengers," <u>Toxicology</u> , 1988, 51, Pgs. 119-132
36	HAYES, D. et al., "Amelioration Of Renal Toxicity Of High Dose Cis-Platinum Diammine Dichloride (CPDD) By Mannitol Induced Diuresis," <u>Proc. Am. Assoc. Cancer Res.</u> , 1976
37	INFANTE, G. A. et al., "Chemical radioprotection on biological important compounds," <u>Radiation Research</u> , 1976, Vol. 67, No. 3, Pg. 637
38	JONES, MARK M. et al., "Coadministration of Dimethyl Sulfoxide Reduces Cisplatin Nephrotoxicity," <u>Anticancer Research</u> , 1991, 11, Pgs. 1939-1942
39	JONES, MARK M. et al., "Control of Nephrotoxicity in the Rat during Repeated cis-Platinum Treatments," <u>Journal of Applied Toxicology</u> , 1989, Vol. 9(4), Pgs. 229-233
40	JONES, MARK M. et al., "Control of the Nephrotoxicity of Cisplatin by Clinically Used Sulfur-Containing Compounds," <u>Fundamental and Applied Toxicology</u> , 1992, 18, Pgs. 181-188
41	JONES, MARK M. et al., "Inhibition of cis-diamminedichloroplatinum (II)-induced renal toxicity in the rat," <u>Cancer Chemotherapy and Pharmacology</u> , 1986, 17, Pgs. 38-42

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	42	JONES, MARK M. et al., "Relative effectiveness of some compounds for the control of cisplatin-induced nephrotoxicity," <u>Toxicology</u> , 1991, 68: Pgs. 227-247	
	43	JONES, MARK M. et al., "Thioether Suppression of Cisplatin Nephrotoxicity in the Rat," <u>Anticancer Research</u> , 1991, 11, Pgs. 449-454	
	44	JONES, MARK M. et al., "Thiol and Thioether Suppression of Cis-Platinum-Induced Nephrotoxicity in Rats Bearing the Walker 256 Carcinosarcoma," <u>Anticancer Research</u> , 1989, 9: 1937-1942	
	45	KIDO, K., "The influence of methylmethionine sulfonium chloride (MMSC) on survivors of mice after X-ray irradiation, especially the consideration of the drug effect for the degeneration of intestinal mucosa," <u>Kansai Ika Daigaku Zasshi</u> , 1973, Vol. 25, No. 1, Pgs. 104-107	
	46	KIES, CONSTANCE et al., "Comparative Value of L-, DL-, and D-Methionine Supplementation of an Oat-based Diet for Humans," <u>J. Nutr.</u> , 1975, 105, Pgs. 809-814	
	47	KOPKE, RICHARD D. et al., "Use of Organotypic Cultures of Corti's Organ to Study the Protective Effects of Antioxidant Molecules on Cisplatin-Induced Damage of Auditory Hair Cells," <u>The American Journal of Otology</u> , 1997, 18, 559-571	
	48	KORVER, K. D. et al., "Round window application of D-methionine provides cisplatin otoprotection," <u>Abstracts of the Twenty-First Annual Mid-Winter Research Meeting of the Association for Research in Otolaryngology</u> , February 15-19, 1998, Abstract No. 536, Pg. 135	
	49	KOVACS, V. et al., "Study of the Radiation Protection Effect of Selenium-Methionine by Determining the Paramagnetic Properties of Liver Tissues of Mice," 1988, <u>Acta Physica Hungarica</u> , Vol. 64, No. 1-3, Pgs. 321-326	
	50	MEKHTIEV, M. A. et al., "Radioprotective effect during the separate and combined use of DL-methionine and thyroxine," <u>Database Chemabs Chemical Abstracts Service</u> , Abstract No. 76:54431, 1970 (see also <u>Tr. Inst. Fiziol., Akad. Nauk Azerb. SSR</u> , Vol. 11, pp. 83-100, 1970)	
	51	MELVIK, JAN EGIL et al., "Reduction of cis-Dichlorodiammineplatinum-Induced Cell Inactivation by Methionine," <u>Inorganica Chimica Acta</u> , 1987, 137, Pgs. 115-118	
	52	MERRIN, CLAUDE, "A New Method To Prevent Toxicity With High Doses Of Cis Diammine Platinum (Therapeutic Efficacy In Previously Treated Widespread And Recurrent Testicular Tumors)," <u>Proc. Am. Assoc. Cancer Res.</u> , 1976	

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Application Number	10/694,448
Filing Date	October 27, 2003
Confirmation Number	not yet assigned
First Named Inventor	Campbell
Group Art Unit	not yet assigned

Attorney Docket No. SIU 7398

53	MOLTENI, F. et al., "The use of S-adenosyl-methionine as a radioprotective agent," <u>Gazetta Medica Italiana</u> , 1978, Vol. 137, No. 7-8, Pgs 303-308
54	MONTINE, THOMAS J. et al., "Role of Endogenous Sulfur-Containing Nucleophiles in an In Vitro Model of cis-Diamminedichloroplatinum(II)-Induced Nephrotoxicity," <u>Biochemical Pharmacology</u> , 1990, Vol. 39, No. 11, Pgs. 1751-1757
55	NAKANO, SACHIKO et al., "Potentiation of Cisplatin-Induced Lipid Peroxidation in Kidney Cortical Slices by Glutathione Depletion," <u>Japan. J. Pharmacol.</u> , 1989, 50, Pgs. 87-92
56	ORMOND, T. et al., "Reduced Nephrotoxicity <u>In Vivo</u> and <u>In Vitro</u> of Cisplatin-Methionine Complex," <u>Brit. J. Pharmacol. (suppl.)</u> , 1988, 95, Pg. 584P
57	PRINTEN, KENNETH J. et al., "Utilization of D-methionine during total parenteral nutrition in postsurgical patients," <u>The American Journal of Clinical Nutrition</u> , June 1979 , 32, Pgs. 1200-1205
58	RAVI, RADHIKA P. et al., "Relationship of Pharmacodynamic Effects of Cisplatin to the Glutathione Levels in Cochlea, Inferior Colliculus and Kidney," <u>Pharmacologist</u> , 1991, 33(3), D-19, 402, P. 217
59	RAVI, RADHIKA P. et al., "Diethyldithiocarbamate Protects Against Cisplatin Ototoxicity and Nephrotoxicity," <u>Otolaryngology Head and Neck Surgery</u> , 1992, 107(2), Poster 5, P. 232
60	RESER, D. H. et al., "Physiological evidence for protection from cis-platin ototoxicity by D- and L-methionine <u>in vivo</u> ," <u>Abstracts of the Twenty-First Annual Mid-Winter Research Meeting of the Association for Research in Otolaryngology</u> , February 15-19, 1998, Abstract No. 203, P. 51
61	RHO, M. B. et al., "Structural evidence for protection from cisplatin ototoxicity by both D- and L-methionine <u>in vivo</u> ," <u>Abstracts of the Twenty-First Annual Mid-Winter Research Meeting of the Association for Research in Otolaryngology</u> , February 15-19, 1998, Abstract No. 202, P. 51
62	ROMITO, S., "Sulla radioprotezione cromosomica <u>in vitro</u> : esperienze con metionina, acido aspartico, leucina, lisina," <u>Fracastoro</u> , 1969, Vol. 62, No. 6, Pgs. 576-581
63	SALIKHODZHAEV, Z. et al., "Stimulation of postirradiation recovery of rat haemopoiesis by a cobalt preparation," <u>Database Biosis Biosciences Information Service</u> , Philadelphia, Pennsylvania, Abstract No. 08095385 (see also <u>Radiobiologia</u> , Vol. 31, No. 6, pp. 835-837, 1991)
64	SCHEIN, P. S., "Ethylol™ (WR-2721): a chemoprotective agent for platinum anti-cancer drugs," <u>Speaker Abstracts (XP-002053095)</u>

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--------------------	-----------------

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Sheet	7	of	8	Attorney Docket No.	SIU 7398

	65	SCHWEITZER, VANESSA GAYL, "Cisplatin-Induced Ototoxicity: The Effect of Pigmentation and Inhibitory Agents," <u>Laryngoscope</u> , April 1993, 103, Pgs. 1-52	
	66	SHA et al., "Antioxidant therapy attenuates gentamicin-induced ototoxicity," <u>Abstracts of the Twenty-First Annual Mid-Winter Research Meeting of the Association for Research in Otolaryngology</u> , February 15-19, 1998, Abstract No. 535, P. 134	
	67	SPEER, R. J. et al., "Coordination Complexes of Platinum as Antitumor Agents," <u>Cancer Chemotherapy Reports</u> , 1975, Part I, Vol. 59, No. 3, Pgs. 629-641	
	68	SRINIVASAN, V. et al., "Radioprotection By Misoprostol (PGE, Methyl Analog) In Combination With Vitamin E, Selenomethionine and WR-3689794," <u>Eicosanoids and Other Bioactive Lipids in Cancer, Inflammation, and Radiation Injury 2</u> , edited by K. V. Honn et al., 1997, Plenum Press, New York, Pgs. 791-797	
	69	TOGNELLA, SERGIO, "Pharmacological interventions to reduce platinum-induced toxicity," <u>Cancer Treatment Reviews</u> , 1990, 17, Pgs. 139-142	
	70	TRESKES, MARCO et al., "WR2721 as a modulator of cisplatin- and carboplatin-induced side effects in comparison with other chemoprotective agents: a molecular approach," <u>Cancer Chemotherapy and Pharmacology</u> , 1993, 33, Pgs. 93-106	
	71	VAN DE WATER, T. et al., "Oxidative stress in the inner ear: Combinatorial therapy;" (202) M. B. Rho et al., "Structural evidence for protection from cisplatin ototoxicity by both D- and L-methionine in vivo," <u>Abstracts of the Twenty-First Annual Mid-Winter Research Meeting of the Association for Research in Otolaryngology</u> , February 15-19, 1998, Abstract No. 6, P. 2	
	72	WALKER, ERNEST M., JR. et al., "Methods of Reduction of Cisplatin Nephrotoxicity," <u>Annals of Clinical and Laboratory Science</u> , 1981, Vol. 11, No. 5, Pgs. 397-409	
	73	WARD, J. M. et al., "Modification of the Renal Toxicity of <i>cis</i> -Dichlorodiammineplatinum(II) With Furosemide in Male F344 Rats," <u>Cancer Treatment Reports</u> , 1977, Vol. 61, No. 3, Pgs. 375-379	
	74	WHITWORTH, C. A. et al., "Alpha-lipoic acid as a protective agent against ototoxicity;" (535) S. H. Sha et al., "Antioxidant therapy attenuates gentamicin-induced ototoxicity," <u>Abstracts of the Twenty-First Annual Mid-Winter Research Meeting of the Association for Research in Otolaryngology</u> , February 15-19, 1998, Abstract No. 532, P. 134	

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75	ZEZULKA, ALLISON YATES et al., "Nitrogen Retention in Men Fed Isolated Soybean Protein Supplemented with L-Methionine, D-Methionine, N-Acetyl-L-Methionine, or Inorganic Sulfate," <u>J. Nutr.</u> , 1976, 106, Pgs. 1286-1291	
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